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Refereed paper

The provision and impact of online patient access to their electronic health records (EHR) and transactional services on the quality and safety of health care: systematic review protocol

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ABSTRACT

Background Innovators have piloted improvements in communication, changed patterns of practice and patient empowerment from online access to electronic health records (EHR). International studies of online services, such as prescription ordering, online appointment booking and secure communications with primary care, show good uptake of email consultations, accessing test results and booking appointments; when technologies and business process are in place. Online access and transactional services are due to be rolled out across England by 2015; this review seeks to explore the impact of online access to health records and other online services on the quality and safety of primary health care.

Objective To assess the factors that may affect the provision of online patient access to their EHR and transactional services, and the impact of such access on the quality and safety of health care.

Method Two reviewers independently searched 11 international databases during the period 1999–

2012. A range of papers including descriptive studies using qualitative or quantitative methods, hypothesis-testing studies and systematic reviews were included. A detailed eligibility criterion will be used to shape study inclusion. A team of experts will review these papers for eligibility, extract data using a customised extraction form and use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) instrument to determine the quality of the evidence and the strengths of any recommendation. Data will then be descriptively summarised and thematically synthesised. Where feasible, we will perform a quantitative meta-analysis.

Prospero (International Prospective Register of Systematic Reviews) registration number: crd42012003091.

Keywords: electronic health records, general practice, medical informatics, medical records, patient access to records, primary care, transactional services

Introduction

Record access provides most benefit if used as an integral part of the care process. If patients access their records, particularly in the context of joint decision-making in partnership with their health professionals, the result can lead to improvements in their care.¹

The pros and cons of record access

Patient record access has been described as fundamental to empowerment for patients, but progress to date has been limited by professional resistance and

concerns about security and privacy,^{2–5} and legal constraints.⁶ The tensions between growing consumer demand to access data and a healthcare system not yet ready to meet these demands have escalated in recent years.^{7,8} The allure that an online information provider might link personal records from multiple sources into a readily digestible single record has not been realised.^{9,10}

A national attempt to make an online 'HealthSpace' available to patients failed to engage significant numbers and was consequently abandoned.¹¹ What have been described as straightforward approaches to overcoming the barriers to adoption^{12,13} have been successfully piloted,¹⁴ but not widely adopted. Where

innovators have provided access to records they have found mixed responses. Patients by and large understand their data, but require some education; they are concerned about the risk to privacy, the relative brevity of the record and that mistakes, although few, are clinically significant.¹⁵ Additionally, for children and young people, hybrid access by parents or other family members complicates arrangements further.¹⁶

Online services for patients

A range of online services, also termed 'Transactional services', have been provided; for example, ordering of repeat prescriptions, online booking and cancelling of appointments, and developing the means for secure communication with the practice.¹⁷ (The term 'Transactional services' is used as in the letter from the UK Digital Champion's letter to the UK government.^{18a}) There have been some notable international successes. Kaiser Permanente has had two-thirds of its 3.4 million members sign up for online services; with online booking of appointments, collecting test results and email the most used services.¹⁸ The US Veterans Administration has also managed to register large numbers online with over 600 000 users making over 20 million 'visits' over the Internet by 2008; the most popular service is online repeat prescription requests.¹⁹ Less successful was the implementation of electronic transmission of prescriptions from the general practice to the pharmacy as part of the European eHealth action plan in 2008; the response has been patchy, with Sweden one of the few countries to comprehensively introduce it.²⁰

Who uses online services?

It has been suggested that ease of use, described using a technology-acceptance model, best predicts loyalty to online services.²¹ Online services are said to appeal most to the young, and this has been demonstrated in exploring the potential for delivering sexual health clinics online;²² although others have suggested that there may be greater benefit in the care of older people.¹⁴ Tailored services have been used, and appear to be safe, in a wide range of conditions, including depression, diabetes, breast cancer and renal disease.^{23–26}

Although much has been written about implementing information technology (IT) systems in health care,²⁷ relatively little is known about appropriate implementation strategies for introducing online patient record access.

A working team, comprising academics and healthcare professionals, aims to undertake a systematic review to explore the impact of online access to health records and other online services on the quality and safety of primary health care.

Outcome measures

The outcome measures are quality and safety. As a subjective concept, quality is difficult to define, thus we have taken a focused view using a definition developed for primary care. In health care, quality definitions often include safety.

Over time there has been a shift in health care from a reliance on professional judgement to measure quality to the systematic measurement of differences in the quality of care.²⁸ The Agency for Healthcare Research and Quality (AHRQ) defined quality as:

Doing the right thing, at the right time, in the right way, for the right person – and having the best possible result.²⁹

The English Department of Health has used different definitions of quality;^{30,31} however, for the purposes of this study we have elected to use the following quality measures developed in the context of UK primary care:

- accessibility – a systematic review of service innovation was equivocal,³² albeit there was little provision of online access to records when this was completed;
- clinical and interpersonal effectiveness for individual patients;
- equity and efficiency of the service provided;^{33,34}
- patient safety is an integral part of quality, although most systematic reviews of electronic health records (EHR) systems focus on computerised physician order entry and prescribing safety.^{35–37}

Description of the intervention: online access to records and services

Our definition of 'online access' is that people can log on from their home, workplace or mobile computing device to access all or part of their medical record, provided by a primary care computer system vendor, and associated transactional services, in a secure and safe environment.

We also include access to other EHR systems primarily intended to be used for ambulatory care.

Online services are of two types: administrative or clinical care. Administrative tasks include booking or cancelling an appointment and requesting a repeat prescription. Typically, these are functions carried out by practice support staff. Clinical care would include email questions to the doctor or other clinical staff, specific informational support related to a clinical illness and test results.

How the intervention might work

We can hypothesise how online access to EHR and service might improve quality, by providing 24/7 access to records and online services; facilitating communication between clinician and patient, thereby improving patients' experiences of primary health care. The low costs of online access may also improve service efficiency, and clear signposting of available services – which might be provided in many languages – may ensure greater equity. However, it is also possible to imagine barriers to patient access and that inappropriate access to records might take place – as a result of both hacking into systems and coercion to reveal record content, and this may enhance the digital divide.^{38,39}

Why it is important to carry out this review

This review is timely because of the policy context; it is written for those who are looking to implement current policy. The NHS Future Forum proposed that patients should have online access to their records;⁴⁰ and subsequently, the UK government announced in its health strategy that all patients are to have access to their own health record by 2015.⁴¹ The Royal College of General Practitioners (RCGP) produced guidance conceived by pioneers of patient record access in 2010.¹²

The purpose of this review is, ultimately, to inform health service commissioners of the benefits and harms that might arise through the provision of online access to ambulatory care records and to identify technologies and business processes that need to be in place if online access is to be a reality in 2015. The aims and objectives of the review have been framed to identify the barriers and facilitators to providing access to online records and transactional services; and then to explore how access to these services might impact on the quality and safety of health care. The patient, the technology and the ambulatory care team are considered the key actors. They all need to be able to interact for online access and services to be successful.

Aims

The aims of this review were to assess the factors that may affect the provision of online patient access to their EHR and transactional services and the impact of such access on the quality and safety of health care.

Objectives

The objectives of the review fall into two categories, namely to: (1) identify and understand the barriers and facilitators to providing online access to records and transactional services in ambulatory care; and (2) assess the benefits and harms of online access to records and transactional services in ambulatory care and how they affect the quality and safety of health care.

Key research questions

We have identified four key research questions that we intend to answer in this review, developed from an approach used in a recent systematic review.⁴² They cover the impact of online patient access and provision of transactional services; practice and EHR system factors.

Key question 1

What is the association between online patient access to their EHR and:

- utilisation of health care;
- health outcomes, including patient safety;
- patient experience and satisfaction;
- adherence;
- equity; and
- efficiency?

Also, wherever possible to identify the impact of online patient access to their EHR.

Key question 2

What is the association between online patient access to transactional services provided as part of their ambulatory care EHR and:

- utilisation of health care;
- health outcomes including patient safety;
- patient experience and satisfaction;
- adherence;
- equity; and
- efficiency?

Also, wherever possible to try to identify the impact of online patient access to transactional services.

Key question 3

What is the association between the practitioner and healthcare team being provided with:

- education and staff training;
- making workload and workflow changes;

- achieving regulatory compliance;
- business process changes for ambulatory care;
- and patient uptake of online access and transactional services as part of their ambulatory care?

Key question 4

What is the association between:

- IT developments which provide records access;
- systems to enhance privacy and security;
- usability and accessibility of transactional services;
- business process for technical development of EHR systems, including lead time in their development;

and patient uptake of online access and transactional services as part of their ambulatory care?

Method

Overview and key definition

We define 'online access' as the process of a patient, or their authorised carer or guardian, logging on to access all or part of their medical record and associated transactional services from their home, workplace computer or mobile computing device, in a secure and safe environment.

In undertaking this review we are also interested in *how* types of intervention might be delivered in the period from the completion of this review to the proposed implementation date, 2015. Understanding how interventions might be implemented may give rise to greater knowledge about the issues which may facilitate or be a barrier to this process.

The research will ultimately identify further areas where research is needed, for example, recommendations for further methods to assess and evaluate care quality, efficiency and safety effects.

Criteria for including studies in this review

Eligible study designs

We will include a range of study types; including:

- descriptive qualitative studies to explore attitudes and experiences;
- descriptive quantitative studies, such as surveys, cohort or longitudinal studies, including log file analysis;
- usability studies of pilot or prototype systems;
- studies that test hypotheses, for example, randomised trials;

- economic and workflow analyses; and
- secondary research of any of the above such as systematic reviews.

All evidence included in the study will be assessed to determine the quality of evidence and strengths of recommendation. This approach has been used in a recent review in this domain.⁴²

Eligible participants and care setting

The included studies and reports will be relevant to the population which the review encompasses, i.e. medical and other health professionals, patients, carers and system suppliers. We also include the technology that enables the interaction, because we see the computer and the technology as a third actor in the consultation.⁴³ We will focus specifically on studies based in general practice, primary, family or ambulatory care facilities in any country but will exclude studies performed in secondary care or the community.

Eligible interventions

Any study included in the review must relate to EHR systems used in primary care. The types of intervention will be classified by whether they are principally designed to impact on patients, clinicians or are technical in nature (Box 1). We will also explore whether usage of online access is primarily synchronous or asynchronous, and if these interactions are about the direct delivery of health care (e.g. explaining test results), or about the administration of health care (e.g. booking an appointment). For clinicians and healthcare teams, we are looking for interventions that facilitate and inhibit the adoption and uptake of technology. Although generic models exist for assessing the barriers to using records or health IT systems in general,^{44,45} much less is known about what interventions might influence adoption and use. We have suggested looking for interventions that improve skills and competency, enable incorporation into workflow, and that help achieve regulatory compliance. Finally, we are exploring the technical aspects of the intervention. These include technical issues related to accessibility, security and privacy; additionally they will explore interventions that drive the business process so that systems are developed which meet the policy requirement (i.e. delivery of online access by 2015).

We will also record the time taken for implementation of the interventions reviewed, because our output is intended to inform commissioners of health services who wish to implement change between 2013 and 2015, albeit that some vendors and practices have implemented online access already.¹ For example, it is unlikely that a diffusion of innovation model for the

Box 1 Framework of the types of intervention that might have an impact on the provision or uptake of online access to and utilisation of transactional services

1. Patient interaction and services

- Patient themselves and/or patient's carer, advocate or other representative.
 - Reports of uptake effect on: concordance, quality of life, empowerment.
 - Measures to overcome inequities – economic and computer literacy.
 - Health outcome measures.
- Interactive
 - Medical care related:
 - (i) symptom triage, e.g. by email, web forms, web chat;
 - (ii) online consultation (we will exclude telephone consultations);
 - (iii) dedicated personal electronic health record for supporting self-management of long-term conditions.
 - Administration of care:
 - (i) tracking results or services;
 - (ii) look-up of care due;
 - (iii) guidance on the process of or eligibility to services.
- Asynchronous:
 - Medical care related:
 - (i) access lab results;
 - (ii) tools to inform shared decisions on immunisation, screening, etc.;
 - (iii) check status, e.g. immunisation, screening, clinical review;
 - (iv) request prescription medications;
 - (v) review previous care provision;
 - (vi) links to further information, such as administration of care;
 - (vii) appointment booking and cancellation;
 - (viii) request repeat prescription;
 - (ix) guidance on eligibility to services.

2. Practitioner and practice staff impact

- Skills and competencies to support and to enable patient interaction with the ambulatory electronic health record system.
- Education and training in safe and effective use (by practitioners and staff).
- Change management, pace of change issues – given policy commitment to implement in 2015.
- Workflow and impact on the organisation and delivery of health care.
- Workload.
- Type of cases and time of delivery (e.g. home working in evenings).
- Balance (e.g. effect on traditional consultations).
- Audit of use and quality and use of the system, including inequalities in access and service use.
- Business models and processes that form barriers of facilitate uptake.
- Financial incentives.
- Non-financial.
- Regulatory compliance.
- Personal for individual professionals [e.g. General Medical Council (GMC) for doctors].
- Legislative (e.g. data protection, equity audits for public services).
- Regulatory [e.g. Care Quality Commission (CQC)].
- Policy compliance (e.g. Commissioners of Health Care and its support services).

3. Technological aspects

- Bandwidth and accessibility requirements (including whether from PC, mobile technology or via social media).
- Identification of individuals.
 - Ensuring authorised access.
 - Provision for vulnerable persons.
- Technological aspects of auditing of use and uptake, and detecting inappropriate use and abuse.
- Security and privacy measures.
- Incorporation of booking, tracking and other established transactional technologies.
- Novel technologies (e.g. Machine learning to answer patient questions).
- Timescale and business process required for implementation.
 - Development of requirements analyses, use-cases and business process modelling.
 - Agile or waterfall methods of application development and implementation.
 - Impact of regulatory compliance for medical applications.

implementation of a new intervention would deliver the change required in the proposed timescale.^{46,47}

At present, we are unable to predict the key characteristics of EHR implementations, such as how to measure the time taken for implementation; for example, when does an intervention start and finish? In order to fully understand these issues we have included several questions in the data extraction form (DEF) which will aid exploration into this area.

Ineligible interventions

We will not include studies about the implementation of EHR in general, which health professionals only can access. Exclusions include target data, EHR which are already being rolled out for the benefit of clinical staff to record and retrieve information. Studies that examine patient access to health records which are not online are also excluded (i.e. access to paper records). Studies that focus on patient access to their EHR in a clinical setting, i.e. studies of screen sharing, or pre-consultation questionnaires within the practice premises, will also be excluded (Figure 1).

Exclusion summary:

- Provision of clinicians or practice staff online or remote access to their workplace computer, unless it is to provide online transactional services to patients.

- Online/eHealth health promotion tools, there is a large literature and other systematic reviews already of these telehealth/telemonitoring of chronic and other conditions. Again there is a large literature, and other systematic reviews, about this already.
- Administrative tools that do not form part of an online access or a transaction about the administration of direct patient care. For example, invitations to patient groups, or to participate in research projects.
- Access to records, not provided online.
- Systems and services based in social/community/secondary/tertiary care, unless directly relevant to primary care.
- Insights from countries with demonstrably very different health systems or models to UK primary care. For example, where a fee for service or avoiding a fee for service, or the lack of a billing process either promotes or is a barrier to the uptake of services.
- Quality measures [e.g. NHS Information Centre Quality and Outcomes Framework (QOF) summary data or NHS Comparators data] on central repositories will also not be considered as part of online access, nor will feedback comments by patients (e.g. NHS Choices) about their practice. Although an online complaints system held within

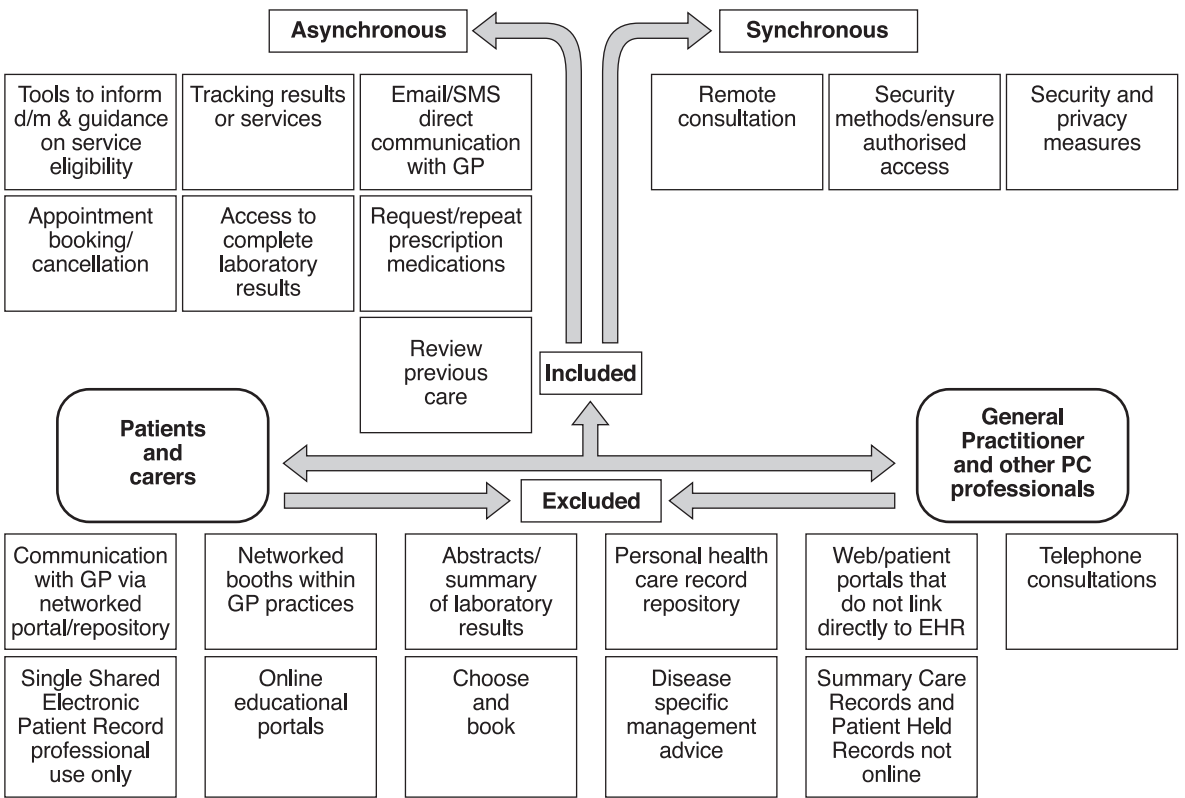


Figure 1 Inclusion and exclusion criteria

the practice would be included as a transactional service.

- Ambulatory care settings with either no EHR or one to which professionals and managers alone have access.

Types of outcomes: primary and secondary

Our primary outcome measure is change in quality or safety as a result of the implementation or utilisation of online records or transactional services. Our key questions are similar to those used in a systematic review specifically looking at records access and secure email.⁴²

Secondary outcome measures include: quality measured using validated instruments, accessibility, clinical and personal effectiveness for individual patients, and the equity and efficiency of the services delivered to populations. We are also interested in a range of additional outcome measures related to healthcare professional and technological interventions which enable or form barriers to the adoption and utilisation of online access and services.

Search methods for the identification of studies

Published literature

Other relevant literature may include reports, book chapters and conference abstracts. This review will include all such sources, especially those of international origin. Because recently published research will be of keen interest, we will restrict our search to between 1 January 1999 and 1 September 2012. All efforts will be made to include foreign language literature.

The selection of studies includes both primarily, online literature databases and non-database materials.

Primarily, online databases:

- the Cochrane Library, including the Cochrane Effective Practice and Organisation of Care (EPoC) registry of QI strategies, the Cochrane Database of Systematic Reviews (CDSR) and the Database of Abstracts of Reviews of Effectiveness (DARE);
- general medical bibliographic databases (MEDLINE, Embase, CINAHL);
- OpenGray/SIGLE (System for Information on Grey Literature) access to the database of European grey literature;
- PsychInfo;
- conference proceedings (list relevant conference bodies, i.e. HC2012);
- unpublished data from active authors; and

- screening of reference lists from retrieved articles.

Non-database materials may also be searched and these may include:

- policy documentation;
- communications brochures;
- public information documentation; and
- literature signposted from within the RCGP online patient access programme.

Unpublished/in-progress work

The 'Evidence and Evaluation' Working Group conducting this review is part of an online records initiative.

We have developed two publically accessible online data entry forms to use to submit evidence. One for case studies (www.clininf.eu/projects/patient-access/case-study-form.html) and a second for literature or other publications (www.clininf.eu/projects/patient-access/reference-form/reference-submission.html).

We will cross-reference items collected using the online data entry forms to references originating from the database searches. This online collection of evidence was promoted to all 46 000 GPs who are members of the RCGP via the Chair's blog and the *RCGP News*.

Search strategies

Search strategies will be run across databases to identify studies and materials that focus on patient access to online records and the range of transactional services offered in primary and ambulatory care.

To be eligible, literature needs to address 'access to online records', and other keywords present in the framework outlined in Box 1, with keywords in the full text and abstract.

These are only preliminary terms. Further time will be spent on separate databases to find primary MeSH (Medical Subject Headings) terms.

Storing of results

Results from these searches will be stored using Endnote v4 and, where copyright allows and it is feasible, in our online repository. At this stage, de-duplication of literature will take place, and duplicated items removed. An initial screening of titles and abstracts against the inclusion criteria to identify potentially relevant papers will be performed by a small group of members of the study team (including SdeL, MC and FM). If further information is needed to inform a decision, the full text will be retrieved and a final decision made. Studies will be excluded at this point if articles are without either abstract or full text availability. A kappa score will be used to measure inter-rater

Box 2 Extract of search string

((MH "Medical Records") OR (MH "Health Records, Personal") OR (MH "Records as Topic") OR "medical record*") AND ((web* OR internet OR www OR electronic* OR online OR electronic mail* OR email* OR e-mail* OR web mail* OR webmail* OR internet mail* OR messag*))

OR

(online OR web* OR internet) N4 (consult* OR service* OR intervention* OR therap* OR treatment* OR counsel*)

OR

((MH "Caregivers") OR (patient* OR carer* OR consumer*)) N5 ((MH "Computer Communication Networks") OR (MH "Electronic Mail") OR (electronic mail* OR email* OR e-mail* OR web mail* OR webmail* OR internet mail* OR messag*))

OR

(MH "Remote Consultation") OR "remote consultation" OR "remote communicat*" OR "remote access"

AND

(MH "General Practice") OR (MH "General Practitioners") OR (MH "Family Practice") OR (MH "Primary Health Care") OR (MH "ambulatory care") OR "primary care" OR "community-based provider"

agreement.^{48,49} The Cochrane Collaboration suggests that a kappa statistic may be calculated for measuring agreement, although it is not calculated as standard in Cochrane reviews.⁵⁰

The remaining studies will be retrieved in full either by links to the full text or through hard copies. Members of the review group may, at this point, request that a study be excluded, either because, on further inspection, the item fails to meet the inclusion criteria or on the basis of poor quality. The reviewer will use an exclusion form to identify reasons for items to be rejected at this stage. The items excluded at this stage will be listed. Full-text items will then be divided equally between group members for review. It is envisaged that each reviewer will receive around five, but not more than ten items of literature. This number may be revised depending on the final number of studies found. All efforts will be made to accommodate reviewers' requests to review specific types of papers. However, to avoid any type of bias and to maintain equality between reviewers, in the first instance papers will be distributed at random between the review group.

Online evidence repository

An online repository of available evidence will be created providing the article for full review as well as linking with other working groups to flag relevant and significant findings as they arise.

Analysis and rating of papers will be performed using the online mechanism to feed materials to working group members.

Quality assessment***Choice of tool to determine quality***

The GRADE tool recommended by the EPOC and Cochrane will be used to determine the quality of the evidence and strengths of recommendation that might be made on the basis of the evidence presented.^{51–53} It grades the strength of each important outcome and looks at important considerations around study design and study quality.⁵⁴ GRADE cannot be used for epidemiological, survey or qualitative research.

Refining the data collection forms and training the assessors

We conducted two exercises to refine the data collection tools and ensure consistency in the reviews.

First, we sent out our DEF and GRADE instrument to all our reviewers and the same two papers. We asked them to review the DEF for ease of use. As part of the DEF refinement exercise, reviewers were also asked to classify papers according to the framework developed for this systematic review (Box 1).

Second, each reviewer was sent a second set of papers to assess. Differences between reviewers were noted and where they varied greatly this was discussed with them by SdeL, FM or MC. The study team will also hold a review when a third of the reviews are complete and will provide reviewers with general as well as individual-specific feedback.

Data analysis and synthesis

The DEF will assist each reviewer to retrieve the core contents of each study and will aid in the organisation of material before analysis. These DEFs will be collated and organised initially according to the key questions, as outlined in the Aims section and/or by the framework of types of interventions as described in our framework (Box 1), and inter-rater reliability will be tested.

We expect there to be mixed methodologies between qualitative and quantitative studies. We will, where relevant, complete a meta-analysis if there is no significant heterogeneity and sufficient quantitative data are available, and meta-regression if there is heterogeneity and effect modifiers are reported often enough.

We will use theoretical models based on the themes identified. We will pilot these on an initial series of studies and then finalise our data-collection method.

Finally, evidence will be tabularised showing the study characteristics and results for all included studies, organised by either our research questions or by the framework of types of interventions as described in Box 1. This process will enable us to compare study characteristics, methods and findings and synthesis evidence across themes.

Assessment of risk of publication bias

We will list all excluded studies and use the Cochrane Collaboration's risk of bias tool to assess trials, questionnaires or other relevant studies. If we have reasonable suspicion that publication bias may be an issue, we will use a funnel plot to explore further.⁵⁵

We plan to use GRADE to assess the risk of bias in primary studies. A summary table will be used to plot risk of bias assessments, and this can be created using RevMan.⁵⁶ The tool has six domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues.⁵⁶

Dissemination

Dissemination of interim findings will be signposted to other working groups and other stakeholder groups, with other approaches encompassing conference presentations and submission to relevant peer review journals.

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CONFLICTS OF INTEREST

None declared.

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